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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,178	03/12/2004	Joc W. Ferguson	31132.237	8149

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EXAMINER	
REIMERS, ANNETTE R	
ART UNIT	PAPER NUMBER

3733

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/799,178	FERGUSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Annette R. Reimers	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 July 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 4-27 is/are pending in the application.
- 4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4-12 and 21-27 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 04 October 2004 and 17 July 2006 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

It is noted that full faith and credit is being given to the action by the previous Examiner in accordance with MPEP 706.04.

### ***Double Patenting***

Claim 1, 11, 12, 21 and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 and 22-24 of copending Application Number 10/799835. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim an assembly with a distractor with a first and second arm, a first and second anchoring device (fastener), an attaching instrument, and a shaping (milling) instrument. Both inventions are for preparing an intervertebral disc space between a pair of vertebral bodies to receive a prosthesis. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 21-23 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 21, lines 5-6, applicant positively recites part of a human, i.e. "a first anchoring device coupled between the first distracting arm and the first vertebral body". In claim 21, lines 9-10, applicant positively recites part of a human, i.e. "a second anchoring device coupled between the second distracting arm and the

second vertebral body". Thus, claims 21-23 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 10, 21 and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Bertangnoli (US Patent Publication Number 2005/0021040), cited by applicant.

In regards to claim 1 and 21, Bertangnoli discloses an assembly having a distractor (5) with a first (11) and second (12) distraction arm (in parallel relation), and a first (19) and second (23) anchoring device (see figures 1 and 2). In regards to claim 2-4, the first anchoring device can move in a sagittal, pivotal, or linear movement (via the pivot hinge). In regards to claim 5 and 21, the first anchoring device (19) has a nonthreaded pivot mechanism (35) and first distracting arm (11) has a pin (40). It is

noted that a pin is a slender usually cylindrical piece of wood or metal for holding or fastening parts together. In regards to claim 6, the first anchoring device has an elongated shaft (see figures 1 and 2) and first distracting arm (11 or 12) has an elongated recess (see figures 1 and 2). In regards to claim 10, the first anchoring device has an adjustable seat (36). Regarding claims 24-27, Bertangnoli discloses a first distracting arm (17) including a side wall with an elongated slot (see figure 2), an anchoring device (11), a connection projection (16), a second distracting arm (21) in parallel relationship to the first distracting arm, an internal bore surrounded by the side wall and in communication with the elongated slot, a pin and a C-shaped opening (see figure 2).

It is noted that while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429,1431-32. (see also MPEP 2114, R-1).

Furthermore, with regard to the statement of intended use and other functional statements, e.g. configured to receive a fastener, they do not impose any structural limitations on the claims distinguishable over Bertangnoli, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the

manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9, 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertangnoli (US Pat App Pub 2005/0021040) (in the IDS) in view of Kim (US Pat App Pub 2003/0055430) (in the IDS).

In regards to claims 7-9 and 22, Bertangnoli discloses the claimed invention except for having an alignment guide. Kim discloses a distractor device with an alignment guide(42, figure 11 a-c). Kim shows the alignment guide is placed between the first and second anchoring device, has a pair of apertures, and a restraint pin from the first anchoring device (38, Bertangnoli figure 3) can pass through the apertures. This allows proper alignment of the assembly on the spine (paragraph 5). It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Bertangnoli, including an alignment guide in view of Kim in order to have proper alignment of the assembly on the spine.

In regards to claim 11 Bertangnoli discloses the claimed invention except for having a measurement instrument. Kim discloses a distractor device with a

measurement instrument, which allows the user to measure between two points. It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Bertagnoli, including a measurement instrument in view of Kim in order to have the measurement between two points.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bertagnoli (US Pat App Pub 2005/0021040) (in the IDS) in view of Michelson (US Pat App Pub 2002/0058944).

Bertagnoli discloses the claimed invention except for having a shaping instrument. Michelson discloses a shaping instrument (100) that provides a space for a disc. It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Bertagnoli, including a shaping instrument in view of Michelson in order to make a space for the disc.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bertagnoli (US Pat App Pub 2005/0021040) (in the IDS) and Kim (US Pat App Pub 2003/0055430) (in the IDS) as applied to claim 22 above, and further in view of Michelson (US Pat App Pub 2002/0058944).

The combination of Bertagnoli and Kim discloses the claimed invention except for having a shaping instrument. Michelson discloses a shaping instrument (100) that provides a space for a disc. It would have been obvious to one skilled in the art at the time the invention was made to construct the combination of Bertagnoli as modified by Kim, including a shaping instrument in view of Michelson in order to make a space for the disc.

***Response to Arguments***

Applicant's arguments filed on July 17, 2006 have been fully considered but they are not persuasive. Regarding the provisional double patenting to copending application 10/799,835, applicant has amended claims 1 and 21 with functional language. As stated above, with regard to the statement of intended use and other functional statements, e.g. configured to receive a fastener, they do not impose any structural limitations on the claims. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Applicant is still claiming the same structural limitations disclosed in claims 1-8, 22-24 of copending Application Number 10/799835. Therefore, a provisional nonstatutory obviousness-type double patenting rejection is still valid.

Applicant's arguments fail to comply with 37 CFR 1.111(b), because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

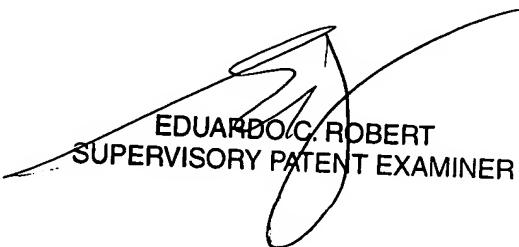
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR



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SUPERVISORY PATENT EXAMINER